NOT FOR PUBLICATION*

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIFOR (INTERNATIONAL) AG and AMERICAN REGENT, INC., Plaintiffs, v. MYLAN LABORATORIES LTD. and SANDOZ INC., Defendants.	Civil Action No. 19-13955 (FLW) **OPINION**

WOLFSON, Chief Judge:

In this claim construction Opinion, the Court construes disputed claim terms across two families of United States Patents, which disclose specific formulations of ferric carboxymaltose, an injectable iron carbohydrate complex, and methods of using those formulations to treat iron deficiency anemia. After reviewing the parties' briefings and exhibits, and holding a *Markman* hearing, the Court construes the disputed claim terms in accordance with the intrinsic and extrinsic evidence, as set forth herein.

I. BACKGROUND

Plaintiffs Vifor (International) AG ("Vifor") and American Regent, Inc. ("American Regent") (collectively, "Plaintiffs") brought the instant patent infringement suit against Defendants Mylan Laboratories Ltd. ("Mylan") and Sandoz Inc. ("Sandoz") (collectively "Defendants").[1] At issue in this claim construction dispute are five patents which share a common

[1] This matter consisted of four separate cases, *see* 3:19-cv-13955; 3:19-cv-16305; 3:20-cv-01647; 3:20-cv-01649, which were consolidated for all purposes, including discovery, case

specification: U.S. Patent Nos. 7,612,109 ("the '109 patent"); 7,754,702 ("the '702 patent"); 8,895,612 ("the '612 patent"); 9,376,505 ("the '505 patent"); and 10,519,252 ("the '252 patent") (collectively, the "patents-in-suit"). (Pls. Opening Br. 1.) Plaintiffs are the assignees of the patents-in-suit. (Mylan FAC at ¶¶ 19-23; Sandoz FAC at ¶ 27.) The patents-in-suit are listed in the Food and Drug Administration's ("FDA") Orange Book for Injectafer (ferric carboxymaltose injection), and they cover an iron replacement product suggested for the treatment of iron deficiency anemia in adult patients. (Pls. Opening Br. 1.)

Specifically, iron deficiency anemia ("IDA") is a condition that develops when body stores of iron drop too low to support normal red blood cell production. (*Id.* at 2.) Prior to the invention of Injectafer (ferric carboxymaltose), intravenous iron therapies for IDA had drawbacks for patients and their healthcare providers because the early infusion products were associated with an elevated risk of unfavorable consequences. Later infusion therapies were generally considered safer, but typically required multiple administrations to deliver the necessary doses of iron. (*Id.*) According to Plaintiffs, this changed, however, with the invention of ferric carboxymaltose, the active ingredient in Injectafer, by Peter Geisser and his team of co-inventors, which is captured in the '109, '505, and '252 patents ("Geisser Family Patents"). Thereafter, Mary Jane Helenek and her colleagues further discovered that ferric carboxymaltose can be administered to patients in a higher dose and in a shorter amount of time than had been deemed advisable at the time. Accordingly, the inventors of the '612 and '702 patents ("Helenek Family Patents") discovered the combination of properties that make the claimed methods of administration possible, to the benefit of IDA patients.

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management, and trial, into one action by Orders dated February 6, 2020 (ECF No. 34) and February 24, 2020. (ECF No. 39).

The instant litigation arose because Defendants filed an Abbreviated New Drug Application ("ANDA") with the FDA to market generic versions of Injectafer. (*See*, *e.g.*, Compl.) In response, Plaintiffs filed the present infringement suit under the Hatch-Waxman Act. (*Id.*) Plaintiffs allege that Defendants' generic product has, or will, infringe certain composition and process claims of the patents-in-suit. (*Id.*) Defendants, on the other hand, have asserted that the patents-in-suit are not infringed, and in that regard, Defendants advanced invalidity theories for each of the asserted claims.

Initially, the parties disputed seven claim terms contained within the patents-in-suit. Prior to the *Markman* Hearing, however, the parties reached an agreement on one of those terms: "iron-carbohydrate complex comprising the reaction product of," and therefore, the Court will not address that term in this Opinion. (*See* ECF No. 97.) The remaining six terms in dispute are divided into two patent families: the Geisser Family Patents and the Helenek Family Patents. Under the Geisser Family Patents, there are three terms in dispute: (1) "maltodextrin," (2) "one maltodextrin" / "each individual maltodextrin," and (3) "subject."[2] The first two disputed claims—those related to maltodextrin—will be construed together, as they turn on the same evidence, and the parties have so argued for purposes of the *Markman* Hearing. As for the Helenek Family Patents, there are also three disputed terms: (1) "the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component," (2) "the iron carbohydrate complex has […] substantially no cross reactivity with antidextran antibodies," and (3) "subject." The following chart provides

[2] On June 25, 2021, Plaintiffs advised the Court that they were "no longer asserting any claims of U.S. Patent No. 10,519,252[, and therefore,] "the claim term 'subject' as used in the '252 patent no longer needs to be construed by the Court as part of the Court's claim construction decision." (ECF No. 186.) Accordingly, the Court will only construe the "subject" term with respect to the Helenek Family Patents.

a summary of the disputed claim terms, and the parties' respective proposed construction for each term:

Disputed Term	Patents/Claims	Plaintiffs' Construction	Defendants' Construction
"maltodextrin"	'109 Patent, Claims 1-16, 19-21, 23-27 '505 Patent, Claims 1-6, 8-24, 26-36 '252 Patent, Claims 1-4, 6-8, 10-16, 18-26	"starch hydrolysate composed of a mixture of saccharides of variable length consisting of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds"	"saccharide(s) of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds"
"one maltodextrin" / "each individual maltodextrin"	'109 Patent, Claims 1-16, 19-21, 23-27 '505 Patent, Claims 1-6, 8-24, 26-36 '252 Patent, Claims 1-4, 6-8, 10-16, 18-26	one/each "maltodextrin," as that term is defined above	Indefinite under 35 U.S.C. § 112
"the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component"	'702 Patent, Claims 4-6, 17-19, 21-22, 24, 31-38, 44-47, 53-54 '612 Patent, Claims 1-5, 10-11, 15-18	"the iron carbohydrate complex has a carbohydrate component resulting in a low risk of anaphylactoid/hypersensitivity reactions, wherein a low risk is an incidence of adverse events associated with the iron carbohydrate complex lower than iron dextran"	Indefinite under § 112. To the extent a construction is possible, it should be construed as a carbohydrate component resulting in a low risk of anaphylactoid/ hypersensitivity reactions, wherein a low risk is an incidence of adverse events lower than dextran.
"the iron carbohydrate complex has […] substantially no cross reactivity with antidextran antibodies"	'702 Patent, Claims 4-6, 17-19, 21-22, 24, 31-38, 44-47, 53-54 '612 Patent, Claim 2	"the iron carbohydrate complex … does not exhibit a substantial antibody/antigen immune response with antidextran antibodies in a clinical setting"	Indefinite under § 112. To the extent a construction may be possible, it must be construed as not limited to requiring cross reactivity with anti-dextran antibodies in a clinical setting.
"subject"	'702 Patent, Claims 4-6, 17-19, 21-22, 24, 31-38, 44-47, 53-54 '612 Patent, Claims 1-5, 10-11, 15-18	"human"	"Mammal to whom the carbohydrate complex is administered"

II. LEGAL STANDARD

A. Claim Construction

The claims of a patent define an inventor's right to exclude. *Philips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The court has the exclusive authority to construe patent terms and determine the correct scope of disputed claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995). The purpose of claim construction is to objectively determine how a person of ordinary skill in the art would understand a claim at the time of the invention. *Phillips*, 415 F.3d at 1313. In construing a claim, the court may examine both intrinsic evidence (*e.g.*, the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (*e.g.*, expert reports, testimony, and anything else). *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

It is well established that claim construction analysis begins with consideration of the intrinsic evidence. *Id.* Intrinsic evidence is considered "the most significant source of the legally operative meaning of disputed claim language." *Id.* In this regard, the court first looks to the words of the claims themselves. *Id.* Claim terms "are generally given their ordinary and customary meaning." *Id.* However, "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning." *Id.* Therefore, it is important that courts examine other components of the intrinsic evidence to determine whether the patentee has given a term an unconventional meaning. *Id.*

The court should then review the patent specification to determine whether the inventor uses terms inconsistent with their ordinary meaning, or explicitly or implicitly defines terms. *Markman*, 52 F.3d at 979. The specification has long been emphasized as "the single best guide to the meaning of a disputed term," and is usually dispositive in claim construction analyses. *Phillips*, 415 F.3d at 1315. The specification "acts as a dictionary when it expressly defines terms

used in the claims or when it defines terms by implication." *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001). Indeed, if the specification "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess," "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

In addition to the claims and specification, the court can consider the patent's prosecution history, which, if in evidence, can inform the meaning of a claim term. *Id.* at 1317. "The prosecution history provides evidence of how the PTO[3] and the inventor understood the patent." *Id.* However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

Finally, a court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. "However, while extrinsic evidence 'can shed useful light on the relevant art,' ... it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Philips*, 415 F.3d. at 1317 (quoting *Vanderlande Indus. Nederland BV v. Int'l Trade Commc'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Extrinsic evidence should therefore be considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. *See Vitronics*, 90 F.3d at 1583.

B. Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572

[3] The United States Patent and Trademark Office.

U.S. 898, 901 (2014). "[D]efiniteness is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed." *Id.* at 908 (citation omitted). "[A] patent must be precise enough to afford clear notice of what is claimed, thereby 'appris[ing] the public of what is still open to them.'" *Id.* at 909 (alteration in original) (citation omitted). At the same time, the definiteness requirement "take[s] into account the inherent limitations of language," and therefore, "some modicum of uncertainty" is permitted. *Id.* (citation omitted). Patents are presumptively valid, and to overcome the presumption of validity, an accused infringer must "show[ ] by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2339 (2011); *Halliburton Energy Sen's., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008).

III. DISCUSSION

A. The Geisser Family Patents

The parties dispute the meaning of "maltodextrin" and "one maltodextrin" / "each individual maltodextrin" found within dependent Claims 1-16, 19-21, 23-27 of the '109 patent; dependent Claims 1-6, 8-24, 26-36 of the '612 patent; and dependent Claims 1-4, 6-8, 10-16, 18-26 of the '252 patent.

1. "Maltodextrin"

As to "maltodextrin," Plaintiffs propose that term means a "starch hydrolysate composed of a mixture of saccharides of variable length consisting of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds." (Pl. Opening Br. at 12.) Defendants, on the other hand, contend that "maltodextrin" means: "saccharide(s) of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds."

At the outset, because noticeable similarities exist between the parties' competing claim constructions, relating to chains of D-glucose units connected by glycosidic bonds, and they refer to saccharides, I note that the dispute turns on three aspects. First, the parties dispute whether "maltodextrin" is a mixture of saccharides of variable length. Second, whether maltodextrin is a starch hydrolysate. Third, whether "maltodextrin" either "consists of" or is "composed of" chains of D-glucose units connected by glycosidic bonds. I will address each of these disputes, in turn.

i. Maltodextrin Refers to a Mixture of Saccharides of Variable Chain Lengths

First, after reviewing the intrinsic and extrinsic evidence, I reject Defendants' proposed construction that "maltodextrin" refers to one or more saccharides. Rather, I adopt Plaintiffs' portion of the term's construction, namely that "maltodextrin" refers to a "mixture of saccharides of variable chain lengths."

Here, relying on the expert opinion of Dr. Geert-Jan Boons, Plaintiff claims that the term "maltodextrin," as used in both the art and the Geisser patents, refers to the carbohydrate produced by the partial hydrolysis of starch, and is thus a "starch hydrolysate." (Pl. Opening Br. at 13-14.) According to Plaintiffs, when hydrolyzed, the starch breaks down to produce a mixture of saccharides of varying chain lengths. (*Id.*) Thus, a POSA would have known that the term "maltodextrin" refers to a mixture of saccharides of varying chain lengths, consisting of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds, that is formed by the partial hydrolysis of starch. (*Id.*) In support of their construction, Plaintiffs further rely on the specification, arguing that it teaches that "the iron preparation is to be producible from easily obtainable starting products and without great effort." (*Id.* at 14) (citing Declaration of M. David Weingarten in Support of Plaintiffs' Opening Markman Brief ("Weingarten Decl."), Ex. 1 at 1:42-44.) According to Plaintiffs, the specification emphasizes that an advantage of the claimed

complex is the "high degree" of commercial availability of the maltodextrin starting material, and as Dr. Boons opines, commercially available maltodextrins as of October 2002 were starch hydrolysates composed of a mixture of saccharides of variable length. (*Id.*) Defendants, on the other hand, submit that their construction is consistent with the claim language chosen by the inventors. (Def. Opening Br. at 10.) Defendants note that claim 1 of the '109 patent and claim 1 of the '505 patent expressly require "at least one maltodextrin," and claim 1 of the '252 patent introduces "maltodextrin" without a modifier, implying it is not limited to the plural. (*Id.*) As such, Defendants rely on *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999), for the principle that "[u]se of the phrase 'at least one' means that there could be only one or more than one." *See also Kistler Instrumente AG v. United States*, 628 F.2d 1303, 1318 (Ct. Cl. 1980) ("Anyone with even the most rudimentary understanding of the English language understands 'at least one piezo-electric crystal' . . . to mean one or more crystals."). Defendants further claim that their construction comports with the specifications of the asserted patents, which use both the singular "maltodextrin" and plural "maltodextrins." (*Id.* at 11.)

The "starting point for any claim construction must be the claims themselves." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298 (Fed. Cir. 1999). Here, in the Geisser Family Patents, the term "maltodextrin" refers to the starting material used to form the claimed iron carbohydrate complex. Indeed, each of the asserted claims of the Geisser patents recites a product comprising oxidized maltodextrin, wherein the maltodextrin, prior to oxidation, possesses a specific dextrose equivalent value. (*See*, *e.g.*, Weingarten Decl., Ex. 1 at Claim 1.) As it relates to whether "maltodextrin" refers to "one or more saccharides," or whether it refers to a "mixture of saccharides of variable chain lengths," however, the Court finds the claims to be silent. Thus, like the parties, the Court acknowledges that the inventors did not "act as their own lexicographer,"

on the definition of maltodextrin. Put simply, neither the claims nor the specifications provide any context or guidance as to this portion of the definition of "maltodextrin," a fundamentally scientific word. Accordingly, "[i]t is permissible, and often necessary, to receive expert evidence to ascertain the meaning of a technical or scientific term or term of art so that the court may be aided in understanding ... what [the instruments] actually say." *Markman*, 52 F.3d at 981 (quoting *U.S. Indus. Chems., Inc. v. Carbide & Carbon Chems. Corp.*, 315 U.S. 668, 678 (1942)).

Here, the extrinsic evidence, specifically the unrebutted expert testimony offered by Dr. Boons, supports Plaintiffs' construction of this portion of the claim. *York Prods., Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1572 (Fed. Cir. 1996). Significantly, Defendants did not provide an expert opinion with respect to the Geisser Patent Family terms; rather, the only expert opinion the Court had to assist it in evaluating the plain and ordinary meaning of "maltodextrin" and "one maltodextrin" / "each individual maltodextrin" was that of Dr. Boons. In that connection, Dr. Boons opined that when hydrolyzed, the starch breaks down to produce a mixture of saccharides of varying chain lengths. (Declaration of Dr. Boons ("Boons Decl.") at ¶¶ 40-44.) Indeed, the Court finds that Dr. Boons' testimony is supported by several reference materials available at the time of invention, including *Starch: Chemistry and Technology* (2nd Ed.), dated before the effective filing date of the Geisser patents, which defines maltodextrin as "a mixture of purified nutritive saccharides obtained by the hydrolysis of starch having a DE[4] of less than 20." (Weingarten Decl., Ex. 22 at 612) (emphasis added). Similarly, the *Handbook of*

[4] The abbreviation "DE" refers to "dextrose equivalent." The parties have agreed that with respect to the Geisser patents, "dextrose equivalent," is defined as the "amount of reducing sugar relative to amount of sugar product, expressed as a dry percentage basis." (Boons Decl. at ¶ 29.) According to Dr. Boons, "the dextrose equivalent value reflects the reducing power of a carbohydrate (*i.e.* the potential for the carbohydrate to reduce another compound and in turn be oxidized to a carboxyl group)." (*Id.* at ¶ 41.)

Pharmaceutical Excipients, identified by Defendants in their Joint Claim Construction and Prehearing Statement, also defines "maltodextrin" as "a nonsweet nutritive saccharide mixture of polymers that consist of D-glucose units, with a dextrose equivalent (DE)." (ECF No. 81-66, Defendants' Joint Claim Construction and Prehearing Statement, Ex. 62 at 317; *see also* ECF No. 81-31, Ex. 27 at 2577 (same).) Further, the Court notes that additional statements offered by Defendants in this case have referred to "maltodextrin" as a mixture of saccharides of variable length. (*See* Declaration of M. David Weingarten in Support of Plaintiffs' Responsive Markman Brief ("Weingarten Resp. Decl."), Ex. I at SANDOZ-FCM000001271; *see also* Weingarten Resp. Decl., Ex. M at Formula 1, ¶ 14, Example 1, Claim 1 (depicting maltodextrin as a mixture of saccharides of variable length); *see also* Weingarten Resp. Decl., Ex. L, MYL-FCARB_0095425.) Finally, Dr. Boons certified that he is unaware of any commercially available maltodextrin not sold as a mixture of saccharides of variable length as of October 2002. (Boons Decl. at ¶ 55.).

Accordingly, the Court adopts Plaintiffs' construction with respect to the first disputed portion of the "maltodextrin" term, specifically it refers to a "mixture of saccharides of variable chain lengths."

ii. The Intrinsic Evidence Does Not Support Inserting a Starch Hydrolysis Requirement into "Maltodextrin"

Next, the parties dispute whether to include "starch hydrolysate" in the definition of maltodextrin. In that regard, Plaintiffs argue that although the claims are silent regarding the process for manufacturing maltodextrin, the prior art consistently defines "maltodextrin" as a product of starch hydrolysis, and therefore, it should be given that meaning. On the other hand, Defendants argue that there is no basis in the claims, specifications, or prosecution history for "importing the additional 'starch hydrolysate' limitation Plaintiffs seek," and therefore, the Court cannot read a limitation into the term that does not exist.

After reviewing the intrinsic evidence, I reject Plaintiffs' proposed construction, and adopt Defendants' construction. Again, the "starting point for any claim construction must be the claims themselves." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298. Here, reviewing the plain and ordinary meaning of "maltodextrin" in the context of the claims, there is simply no indication that the claims themselves insert a specific manufacturing process, or any other limitations, into the definition of the term. Instead, as Defendants point out, Plaintiffs cannot cite a single portion of the claim language or the specifications that limits maltodextrin to production only through the partial hydrolysis of starch. In other words, the claims relate to "maltodextrin," without express limitation on how it is made, and courts are typically reluctant to read into claims particular methods of manufacture where no such process limitations appear in the claims. *See Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) ("The method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. . . . A novel product that meets the criteria of patentability is not limited to the [unclaimed] process by which it is made."); *see also Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir. 1995) (finding a product claim limited to a particular process because the patentee had specifically restricted its claim to a method of manufacture in order to avoid rejection for obviousness); *Orexo, AB v. Mylan Pharm., Inc.*, No. 11-3788, 2014 WL 1302056, at *6 (D.N.J. Mar. 31, 2014) (rejecting a plaintiff's claim construction where neither the language of the patent nor the prosecution history supported the idea that the invention must be limited to a water-free manufacturing process).

Notwithstanding the language of the claims, it is necessary to look to other intrinsic evidence, including the specifications. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). The specification has long been emphasized as "the single best guide to the meaning of a

disputed term," and is usually dispositive in a claim construction analysis. *Id.* The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed. Cir. 2001). In the instant case, the specifications of the Geisser Family Patents, like the claims, are silent as it relates to how maltodextrin is prepared or manufactured. Indeed, Plaintiffs point to only the '109 patent specification's statement that "[t]he usable maltodextrins are easily obtainable starting products, and they are commercially available" and that they have a "high degree of availability . . ., *e.g.*, commercially available additives in the food processing industry." (*See* '109 patent, 2:4-5, 4:62-65.) While Dr. Boons opines that Plaintiffs' construction is appropriate because commercially available maltodextrins as of October 2002 were starch hydrolysates composed of a mixture of saccharides of variable length, courts generally "will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history." *Wasica Fin. GmbH v. Cont'l Auto. Sys.*, 853 F.3d 1272, 1281 (Fed. Cir. 2017). Moreover, although the Court need not consider extrinsic evidence, the extrinsic evidence appears to suggest that maltodextrin, at the time of the claimed invention, was not made exclusively via the hydrolysis of starches, but rather synthetic methods were available for producing saccharides like maltodextrin. (*See* Declaration of Dennis Gregory, Esq. in Support of Defendants' Opening Markman Br. ("Gregory Decl."), Ex. 34 at 23; Gregory Decl., Ex. 36 at 72.)

Accordingly, the Court does not find it appropriate to limit the method in which maltodextrin is manufactured by inserting a process that does not exist in the patent claim language, specifications, or prosecution history.

iii. Maltodextrin is "composed of" chains of D-glucose units connected by glycosidic bonds.

Finally, despite the parties' dispute, the Court does not find a meaningful difference between "consisting of" and "composed of," as it pertains to this specific term. Here, Plaintiffs argue that "maltodextrin" be construed as a "starch hydrolysate composed of a mixture of saccharides of variable length consisting of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds," whereas Defendants submit that the term should mean "saccharide(s) of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds." Specifically, Plaintiffs rely on prior art, arguing that the phrase "consisting of" is "frequently repeatedly" and often used. (Pl. Resp. Br. at 9.) In response, Defendants contend that Plaintiffs' attempted insertion of "consisting of" is improper because that phrase is a term of art in patent law that excludes any unrecited elements. According to Defendants, the asserted claims of the Geisser Family Patents use the open term "comprising," which means that the recited elements are essential, but other elements may be added. (Def. Opening Br. at 15-16) (citing *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997)).

That said, because neither the intrinsic nor the extrinsic record convincingly supports either construction, the Court adopts Defendants' use of the phrase "composed of" to avoid unfairly narrowing the term. *See Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) (explaining that "'[c]onsisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim.").[5] As explained in *Multilayer*

[5] The Court notes that this principle of patent law is well supported. *See*, *e.g.*, *CIAS, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1361 (Fed. Cir. 2007) ("It is ... well understood in patent usage that 'consisting of' is closed-ended and conveys limitation and exclusion. ... For patent claims the distinction between "comprising" and "consisting" is established...."); *Conoco, Inc. v. Energy & Envtl. Int'l*, 460 F.3d 1349, 1359 (Fed. Cir. 2006) ("'[C]onsisting of' is a term of art in patent law with its own construction...."); *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377,

Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1358 (Fed. Cir. 2016), "consisting of," is a "term of art in patent law with a distinct and well-established meaning." (Internal quotations omitted). Thus, "[u]se of the transitional phrase 'consisting of' to set off a patent claim element creates a very strong presumption that that claim element is 'closed' and therefore 'exclude[s] any elements, steps, or ingredients not specified in the claim.'" *Id.* (quoting *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001)). For example, "if a patent claim recites 'a member selected from the group consisting of A, B, and C,' the 'member' is presumed to be closed to alternative ingredients D, E, and F." *Id.* On the other hand, "the alternative transitional term 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements." *Id.* (quoting *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001)).

In sum, the Court finds "maltodextrin" to mean a "mixture of saccharides of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds."[6]

2. "one maltodextrin" / "each individual maltodextrin"

Next, the parties dispute the meaning of "one maltodextrin" / "each individual maltodextrin." Like their proposed construction of "maltodextrin," Plaintiffs assert that their construction of "one maltodextrin" / "each individual maltodextrin," is consistent with the intrinsic record and is supported by prior art. (Pl. Opening Br. at 16-18.) Plaintiffs maintain that the term should be construed using their definition of "maltodextrin," as Plaintiffs defined it above. (*Id.* at

1382–83 (Fed. Cir. 2000) ("The phrase 'consisting of' is a term of art in patent law signifying restriction and exclusion, while, in contrast, the term 'comprising' indicates an open-ended construction.... In simple terms, a drafter uses the phrase 'consisting of' to mean 'I claim what follows and nothing else.'" (citations omitted)).

[6] The Court notes that the claim does not foreclose the possibility that there could be other ingredients in maltodextrin.

16.) Applying that previous definition, which the Court only partially adopted, Plaintiffs argue that based on the claim language contained in Claim 1 of the '109 patent, a POSA would understand that "one maltodextrin" / "each individual maltodextrin" refers to a "single starch hydrolysate composed of a mixture of saccharides of variable length consisting of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds." (*Id.*) (citing Boons Decl. at ¶ 66.) Specifically, they emphasize that Claim 1 of the '109 patent provides that "when one maltodextrin is present [in the reaction], the maltodextrin has a dextrose equivalent of between 5 and 20, and wherein, when a mixture of more than one maltodextrin is present [in the reaction], the dextrose equivalent of each individual maltodextrin is between 2 and 40, and the dextrose equivalent of the mixture is between 5 and 20." (*See* Weingarten Decl., Ex. 1 at Claim 1.) Plaintiffs further highlight that the specification provides examples of iron carbohydrate complexes derived from the reaction product of iron (III) salt and the oxidation of "one maltodextrin" compared to iron carbohydrate complexes derived from the reaction product of iron (III) salt and the oxidation of "a mixture of more than one maltodextrin." Compare Ex. 1 at Example 1 ("100 g maltodextrin (9.6 dextrose equivalent measured gravimetrically)"), with *id.* at Example 4 ("A mixture of 45 g maltodextrin (6.6. dextrose equivalent measured gravimetrically) and 45 g maltodextrin (14.0 dextrose equivalent measured gravimetrically)"). According to Plaintiffs, the starting maltodextrin of Example 1 is "one maltodextrin" as recited in the Geisser patents, while in Example 4, the maltodextrin with a dextrose equivalent of 6.6 and the maltodextrin with a dextrose equivalent of 14.0 are "each individual maltodextrin," that, when combined, constitute "a mixture of more than one maltodextrin." *Id.* While Plaintiffs propose a definition, Defendants, on the other hand, argue that the term is indefinite. (Def. Opening Br. at 16-17.)

Here, I decline Defendants' invitation to find the term indefinite at this juncture. *Horizon Pharma, Inc. v. Dr. Reddy's Lab'ys, Inc.*, No. 15-3324, 2017 WL 5451748, at *5 (D.N.J. Nov. 14, 2017) (finding that the court need not consider indefiniteness arguments at claim construction, as they are better served for summary judgment or trial). While the Court appreciates Defendants' argument that a person of ordinary skill might not be able to determine with reasonable certainty when "one maltodextrin" or "each individual maltodextrin" meets the claimed parameters without first understanding how dextrose equivalent values are determined, the Court also agrees with Defendants' observation that the parties' claim construction dispute for this term is merely a "subset" of the dispute over the "maltodextrin" term. In that regard, the Court finds the term "one maltodextrin" / "each individual maltodextrin" to refer to a single maltodextrin, as that term has been defined above. Moreover, while Defendants argue that Plaintiffs' proposed construction is incorrect because "one maltodextrin" / "each individual maltodextrin" could be construed as having the same meaning as "mixture of more than one maltodextrin," I disagree. When analyzed in connection with the term "maltodextrin" above, "one maltodextrin" would mean a single mixture of saccharides of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds, whereas a "mixture of maltodextrin" refers to a mixture of two or more maltodextrins. As such, I adopt Plaintiffs' construction, using the Court's definition of "maltodextrin" recited above.

B. The Helenek Family Patents

1. "the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component"

With respect to the Helenek Family Patents, the parties first dispute the meaning of "the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component" found within dependent Claims 4-6, 17-19, 21-22, 24, 31-38, 44-47, 53-54 of the '702 patent and

dependent Claims 1-5, 10-11, 15-18 of the '612 patent. Specifically, the parties disagree regarding the meaning of "substantially non-immunogenic" and whether the immunogenicity is assessed for the entire iron carbohydrate complex (*i.e.*, iron and carbohydrate components together), as opposed to just the carbohydrate component. (Pl. Opening Br. at 23.)

Plaintiffs' proposed construction is "the iron carbohydrate complex has a carbohydrate component resulting in a low risk of anaphylactoid/hypersensitivity reactions, wherein a low risk is an incidence of adverse events associated with the iron carbohydrate complex lower than iron dextran." (Pl. Opening Br. at 22.) In support of their position, Plaintiffs argue that their construction is supported by the claims and specifications of the '612 and '702 parents and the state of the art. Plaintiffs explain that the Helenek patent claims concern methods of treatment, including "administering to a subject in need thereof an iron-carbohydrate complex." (*Id.* at 24) (citing Weingarten Decl., Ex. 2 at Claim 1; Weingarten Decl., Ex. 3 at Claim 1.) Therefore, because it is Plaintiffs' view that the Helenek patent claims are directed to clinicians and healthcare providers, they contend a POSA would understand this claim limitation from a clinical perspective. (*Id.*)

Defendants, on the other hand, assert that this term is indefinite under 35 U.S.C. § 112, but to the extent construction is possible, the term should mean: "a carbohydrate component resulting in a low risk of anaphylactoid/ hypersensitivity reactions, wherein a low risk is an incidence of adverse events lower than dextran." (Def. Opening Br. at 18-19.) Defendants first argue that the asserted claims of the Helenek Family Patents require that the carbohydrate component must be "substantially non-immunogenic," however the specifications of the Helenek Family Patents do not provide an explanation of what it means to be "substantially non-immunogenic." (*Id.* at 19-20.) Specifically, Defendants claim that there is a distinction between a "non-immunogenic"

carbohydrate component and a "substantially non-immunogenic" carbohydrate component, but the intrinsic record does not articulate, nor quantify, that distinction. (*Id.*) (Emphasis added). According to Defendants, the intrinsic record's silence is especially problematic because the term "substantially non-immunogenic" does not have an ordinary meaning in the art. Defendants claim that although "immunogenic" is well understood in the art, "substantially non-immunogenic" does not have an established meaning. (*Id.* at 20.) Therefore, because "substantially non-immunogenic" does not have an ordinary meaning in the art, and the specification does not provide insight for a POSA to understand the meaning, the claim is indefinite. (*Id.*) (citing *In re Mobile Telecommc'ns Techs. LLC*, 265 F. Supp. 3d 454, 474 (D. Del. 2017)) ("Because 'substantially' is a term of degree, the patent must provide 'some standard of measuring that degree' such that the claim language provides 'enough certainty to one of skill in the art when read in context of the invention.'").

Moreover, Defendants argue that even if "substantially non-immunogenic" is subject to construction, the Court should adopt the Patent Trial and Appeal Board's ("PTAB" or the "Board") prior construction that "the term 'substantially non-immunogenic carbohydrate component' only requires an assessment of the immunogenicity of the carbohydrate component." (*Id.* at 21) (citing *Pharmacosmos A/S v. Luitpold Pharms., Inc.*, IPR2015-1490, 2017 Pat. App. Lexis 3422, at *4 (PTAB Jan. 4, 2017)). According to Defendants, in that decision, the Board "expressly disagreed 'with Patent Owner that the claims require an assessment of the immunogenicity of the iron carbohydrate complex as a whole.'" (*Id.* at 21-22.) Thus, Defendants urge this Court to disregard Plaintiffs' attempt to re-argue this failed position. Finally, Defendants also highlight that Plaintiffs have prosecuted additional patents in the Helenek Patent Family that include claims requiring

"substantially non-immunogenic iron carbohydrate complex," and that this Court may consider these later prosecutions in deciding claim construction here. (*Id.* at 22.)

At the outset, I address Defendants' contention that the term is indefinite based on its use of the word "substantially." The word "substantially" is not "inherently indefinite." *Elm 3DS Innovations, LLC v. Samsung Elecs. Co.*, No. 14-1430, 2020 WL 1850657, at *6 (D. Del. Apr. 13, 2020). "Substantially" can be used "when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002). However, when substantially is used as "a word of degree," the court has to "determine whether the patent provides some standard for measuring that degree." *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010) (quotation omitted). Otherwise, the patent fails to allow a person skilled in the art to compare potentially infringing products and determine "whether interference ... is substantial." *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) (quoting *Enzo*, 599 F. 3d at 1336). Here, the specification accomplishes that purpose. The specification identifies iron dextran as an objective benchmark against which to assess immunogenicity. (*See* Responsive Declaration of Dr. Coyne ("Coyne Resp. Decl.") at ¶¶ 22-27.) The specification teaches that the focus of the claimed invention is obtaining an iron carbohydrate complex that is <u>less</u> immunogenic (*i.e.*, results in a lower incidence of anaphylactoid/hypersensitivity reactions) than iron dextran. Therefore, as explained by Dr. Coyne, a POSA would understand an iron carbohydrate complex with a "substantially nonimmunogenic carbohydrate component" to be less immunogenic than iron dextran as assessed by a lower incidence of anaphylactoid/hypersensitivity adverse events. (Coyne Resp. Decl. at ¶ 25.) Accordingly, I do not find this term to be indefinite on its face. That said, "[w]hile the court recognizes that a determination of indefiniteness is necessarily intertwined to

some degree with claim construction, it is clear that the court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness." *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, No. 02-148, 2003 WL 124149, at *1 (D. Del. Jan. 13, 2003) (citing *ASM America, Inc. v. Genus, Inc.*, 2002 WL 1892200, *15 (N.D.Cal. Aug. 15, 2002)) (recognizing that claim construction must proceed before an indefiniteness challenge); *see also Intervet America, Inc. v. Kee–Vet Labs.*, 887 F.2d 1050, 1053 (Fed.Cir.1989). Thus, the Court's position at this time does not, however, represent an actual adjudication on Defendants' indefiniteness defense. Rather, the Court simply finds that the claim is sufficiently definite to survive claim construction. Defendants may pursue this defense at trial.

Turning to the substance of the term's construction, it is clear that the parties agree that in the context of the '612 and '702 patents, "substantially nonimmunogenic" requires a "low risk of anaphylactoid/hypersensitivity reactions," measured by relative incidence rates of adverse events. Thus, that portion is not disputed. However, the parties disagree on whether immunogenicity should be assessed for the entire iron carbohydrate complex (*i.e.*, iron and carbohydrate components together), as opposed to the carbohydrate component alone.

Here, I find that Plaintiffs' construction is inconsistent with the intrinsic evidence, including the Helenek Family Patent claims and specification,[7] and therefore, I adopt Defendants' construction. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1317 (Fed. Cir. 2014) (refusing to "import[] an extraneous adjectival modifier into the claim, which, in effect, impermissibly rewrites the patent's claims"); *see also Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 647 (Fed. Cir. 1994) (rejecting patentee's proposed claim construction that would, "in

[7] The '612 and '702 patents share a common specification. For simplicity and consistency, all citations to the specification refer to the '702 patent, attached to the Weingarten Decl. as Exhibit 2.

effect, rewrite its patent claims to suit its needs in this litigation"). In that regard, I agree with the findings of the PTAB in *Pharmacosmos A/S v. Luitpold Pharms., Inc.*, IPR2015-1490, 2017 Pat. App. Lexis 3422, at *4 (PTAB Jan. 4, 2017). There, the PTAB construed the same claim term in the '702 patent, and it rejected the identical construction proposed by Plaintiffs in this case. To be clear, the PTAB agreed with the petitioner that "the language of the term "substantially non-immunogenic carbohydrate component" itself only requires an assessment of the immunogenicity of the carbohydrate component," and disagreed with the patent owner that "the claims require an assessment of the immunogenicity of the iron carbohydrate complex as a whole." *Id.* (emphasis added.) In adopting the construction proposed by Defendants, here, the PTAB reasoned that the specification of the '702 patent also supports a finding that the term "substantially non-immunogenic carbohydrate component" is limited to the carbohydrate component as opposed to the iron carbohydrate complex as a whole. *Id.* Specifically, the specification teaches that "previously available iron dextran products suffered from a 'high incidence of anaphylactoid reactions ... believed to be caused by the formation of antibodies to the dextran moiety,'" while "'[o]ther parenteral iron products (*e.g.*, iron sucrose and iron gluconate) do not contain the dextran moiety, and the incidence of anaphylaxis with these products is markedly lower.'" *Id.* (citing Weingarten Decl., Ex. 2, '702 Patent at 1:53–57 and 11:3–4) ("non-immunogenic carbohydrate component; no cross reactivity with anti-dextran antibodies"). Moreover, the PTAB emphasized that "the language of independent claim 1 itself does not require a non-immunogenic complex, but only specifies that the 'iron carbohydrate complex has a substantially non-immunogenic carbohydrate component.'" *Id.*

Accordingly, consistent with the findings of the PTAB, I find that the plain language of the claims, as supported by the specification, unambiguously requires that only the carbohydrate

component of the iron-carbohydrate complex must be substantially nonimmunogenic. Therefore, there is no need to rewrite the claim language as requested by Plaintiffs. The Court need not consider extrinsic evidence and construes this term in accordance with Defendants' proposed construction: "the iron carbohydrate complex has a carbohydrate component resulting in a low risk of anaphylactoid/hypersensitivity reactions, wherein a low risk is an incidence of adverse events associated with the iron carbohydrate complex lower than iron dextran."

2. "the iron carbohydrate complex has […] substantially no cross reactivity with antidextran antibodies"

Next, the parties dispute the meaning of "*the iron carbohydrate complex has […] substantially no cross reactivity with antidextran antibodies*" found within dependent Claims 4-6, 17-19, 21-22, 24, 31-38, 44-47, 53-54 of the '702 patent and dependent Claim 2 of the '612 patent.

Plaintiffs' proposed construction is "the iron carbohydrate complex … does not exhibit a substantial antibody/antigen immune response with antidextran antibodies in a clinical setting." Plaintiffs contend that this construction is supported by the claims, the specification of the '612 and '702 patents, the state of the art, and the prosecution history. (Pl. Opening Br. at 27.) As discussed above, Plaintiffs argue that a POSA would understand these claim limitations from the clinical perspective. (*Id.*) Therefore, Plaintiffs emphasize that a POSA reading the claims would understand that an iron carbohydrate complex that has "substantially no cross reactivity with anti-dextran antibodies" means that the iron complex will not induce a clinically relevant antibody/antigen immune response in the patient. (*Id.*) (emphasis added.) Plaintiffs further argue that "cross reactivity" was defined during prosecution, and therefore, Plaintiffs' construction is supported by the prosecution history. (*Id.* at 28-29.)

Defendants assert that the proper construction of this term is indefinite under 35 U.S.C. § 112, because a POSA would not understand what it means for there to be "substantially" no cross-

reactivity. (Def. Opening Br. at 22-25.) Similar to its argument above regarding "non-immunogenic," Defendants argue that a substance either has cross-reactivity or it does not. (*Id.*) Defendants posit that the term "cross reactivity" has an established meaning in the art, *i.e.*, "[r]eaction of antisera or sensitized cells with different antigens due to some shared antigenic determinants or shared structures within the determinant," and that the use of that term in the Helenek Patents' specification is consistent with the term's ordinary meaning. (*Id.* at 23.) Defendants contend, however, that "substantially no cross-reactivity" has no established meaning in the art, nor is it defined by the specification. (*Id.* at 23-24) (emphasis added.) Put simply, Defendants argue that a POSA understands that antibodies either cross-react with antigens or they do not cross-react at all. (*Id.* at 23.) Moreover, Defendants argue that to the extent a construction may be possible, it must be construed as not limited to requiring cross reactivity with anti-dextran antibodies in a clinical setting. (*Id.* at 26.) Defendants state that cross reactivity does not require a clinical, *i.e.*, human, response, and as argued, *infra*, the term "subject" as used in the Helenek Patents is not limited to humans. (*Id.*)

First, I find that this term, on its face, is definite. Again, "substantially," in this context, is used to communicate degree, and therefore, the Court's analysis turns on whether "the patent provides some standard for measuring that degree." *Enzo Biochem, Inc*, 599 F.3d at 1332. In that regard, I find that it does. As discussed above with respect to "substantially non-immunogenic carbohydrate component," Plaintiffs reason that the specification discloses to a POSA an objective guidepost—immune responses observed with iron dextran. Thus, it appears, for the purposes of claim construction, that a POSA would understand how to determine whether an iron-carbohydrate complex exhibited fewer immunologic adverse events than iron dextran, therefore exhibiting "substantially no cross-reactivity with anti-dextran antibodies." To reiterate, because the term is

not indefinite on its face, it is capable of construction; however, Defendants' indefiniteness argument remains ripe for trial. *See Forta Corp. v. Surface-Tech, LLC*, No. 13-1608, 2015 WL 3756187, at *2 (W.D. Pa. June 11, 2015) (finding that "[s]ince *Nautilus*[*, Inc. v. Biosig Instr., Inc.*, 572 U.S. ——, 134 S.Ct. 2120, 189 L.Ed.2d 37 (2104)] held that a lesser standard must be met to show indefiniteness, it stands to reason that a court may construe a claim term and then later determine that the patent's 'claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.'"); *see also Ansell Healthcare Prod. LLC v. Reckitt Benckiser LLC*, No. 15-915, 2017 WL 1021844, at *2 (D. Del. Mar. 16, 2017) (finding that a defendant was "free to renew its indefiniteness arguments," specifically those related to a term's use of the word "substantially," later in the case). In addition, I note that besides contesting the term's definiteness, Defendants do not appear to take issue with Plaintiffs' proposed construction other than their inclusion of "clinical setting" and "immune response," which the Court addresses below.

Here, I construe the term as: "the iron carbohydrate complex … does not exhibit a substantial antibody/antigen immune response with antidextran antibodies." First, upon review of the intrinsic evidence, I find no support in the claims themselves for Plaintiffs' position that the term requires a clinical response. Indeed, the claims do not expressly use the term "clinical" or "clinically" such that a limitation in this respect would be appropriate. Regardless, even if some ambiguity existed, the Court finds the teachings of the specifications instructive. In that regard, the specifications discuss a "dextran antigenicity test" of VIT-45, which is an early name used for Injectafer®. (*See* '702 patent, 13:14-15.) The information in the specifications regarding that testing appears to be derived from an Investigational New Drug Application ("IND") submitted to the FDA in January 2004. (*See* Gregory Decl., Ex. 29.) The IND states, for example, that "VIT-

45 does not contain dextran and does not cross-react with dextran antibodies," *id.* at 623, and that "[t]here were no specific responses to VIT-45 in a dextran antigenicity text." *Id.* at 616. Notably, the underlying basis for these statements appears to be study VFR043, which is described as "antibody induction," *see id.* at 627, and as explained by Defendants' expert, Dr. Anthony DeFranco, this study involved a preclinical method of assessing cross-reactivity, and the cross-reaction was studied in guinea pigs—not human patients. (*See* Declaration of Dr. Anthony DeFranco ("DeFranco Decl.") at ¶¶ 146-151; Gregory Decl., Ex. 30 at 233.) Thus, the Court is satisfied that a POSA would understand that this term is not limited to outcomes only in humans, and cross-reactivity does not require a clinical response.[8]

While Plaintiffs argue that insertion of the phrase "clinical setting" in the claim construction is supported by the prosecution history, I disagree. (Pl. Opening Br. at 28-29.) Plaintiffs submit that during prosecution of the '549 patent (a patent in the same family as the Helenek patents but not asserted in this litigation), the Applicant argued, and the Examiner accepted, an express definition of "cross reactivity" that focuses on clinical immune response. (*Id.*) Specifically, Plaintiffs explain that the Examiner initially rejected the claims because, based on a prior art reference, "one of skill in the art would expect anti-dextran antibodies to cross react with polyisomaltose." (Weingarten Decl., Ex. 39 at 4.) The Applicant responded, however, with the declaration of co-inventor, Richard Lawrence, who clarified:

> Based on my experience, cross-reactivity at the time of filing was understood as a reaction between an antibody and an antigen (that differs from an immunogen) resulting in an immune response. In other words, mere binding of an antibody and an antigen was not

[8] The Court also notes that as explained below, *infra*, it does not find that the disputed term "subject," as used in the Helenek patents, is limited to humans, and therefore, if the Court were to adopt Plaintiffs' construction related to this term, it would be inconsistent with its broad construction of the "subject" term, as I have defined it.

> understood as "cross-reactivity" in the absence of an immune response.

(*See id.* at Ex. 37, Lawrence Declaration at 2.) The Applicant then further explained that although the prior art disclosed binding to anti-dextran antibodies, "the Office . . . failed to establish that any such binding results in an immune reaction and, as such, the Office . . . failed to show cross-reactivity." (*Id.* at 9-10.) The Examiner subsequently withdrew the rejection following this information. Therefore, according to Plaintiffs, here, by distinguishing the prior art based on its definition that "cross reactivity" does not mean binding absent an immune response, the Applicant demonstrated that, regardless if binding occurs, it is the absence of a clinical immune response that the claim requires. (Pl. Opening Br. at 29.) However, while I agree that this prosecution history supports inclusion of the phrase "immune response" in the definition of the disputed term, the Declaration of Richard Lawrence relied on by Plaintiffs does not provide any clinical limitations as Plaintiffs advocate. Nowhere in the explanation does the Applicant or the co-inventor suggest that the immune response had to occur in a clinical setting.

Accordingly, the Court adopts the following construction without the need for extrinsic evidence: "the iron carbohydrate complex … does not exhibit a substantial antibody/antigen immune response with antidextran antibodies."

3. "subject"

Finally, the parties dispute the meaning of "subject" found within dependent Claims 4-6, 17-19, 21-22, 24, 31-38, 44-47, 53-54 of the '702 patent and Claims 1-5, 10-11, 15-18 of the '612 patent. Specifically, the parties disagree as to whether this term should be limited to mean humans or rather if the term should mean mammals.

Plaintiffs' proposed construction for the term "subject" is "human." (Pl. Opening Br. at 18, 29.) In support, Plaintiffs argue that their proposed construction is consistent with the patent

itself and the doctrine of claim differentiation, which "presume[s] that different words used in different claims result in a difference in meaning and scope for each of the claims." (*Id.* at 18) (citing *Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000); *see also TQ Delta, LLC v. 2WIRE, Inc.*, No. 13-01835, 2017 WL 6435334, at *4, n.2 (D. Del. Dec. 18, 2017) ("The Federal Circuit has applied the doctrine of claim differentiation both within a single patent and within a family of patents.")). Specifically, Plaintiffs highlight that the shared specification of the Geisser Family Patents states that the claimed complexes can serve as medicaments to be "used in human or veterinary medicine." (*Id.* at 19) (citing Weingarten Decl., Ex. 4 at 4:61-62; Weingarten Decl., Ex. 5 at 4:57-58.) As such, the specification provides support for administration in all "animals," which is recited in the claim of the '505 patent. (*Id.* at 19) (citing Weingarten Decl., Ex. 4 at Claims 5, 6, 9, 23, 27.) But the specification also describes advantages of the claimed iron carbohydrate complexes compared to other complexes used as human medicaments. For example, the specification explains that the present invention is advantageous over prior complexes. Therefore, Plaintiffs argue that applying the doctrine of claim differentiation, the use of "animal" in the '505 patent claims must have a different scope from that of "subject" used in the claims of the '252 patent. (*Id.*) (Compare Weingarten Decl., Ex. 4 at Claims 5, 6, 9, 23, 27, with Weingarten Decl., Ex. 5 at Claim 18.) Put simply by Plaintiffs, "animal" is broad enough to correspond with the specification's disclosure of medicaments used in "human or veterinary medicine," while the term "subject" narrows that definition to only mean "human." (*Id.* at 19.) Moreover, narrowing "human or veterinary medicine" to only "human" is appropriate because the specification emphasizes administration to humans, not animals. (*Id.*)

Defendants assert that the proper construction of this term is "Mammal to whom the carbohydrate complex is administered." (Def. Opening Br. at 27.) In support, Defendants argue

that a POSA would understand the term "subject" in the context of the claims and intrinsic record of both the Geisser Family Patents and the Helenek Family Patents to refer to mammals generally, and not just "humans." (*Id.*) According to Defendants, while Plaintiffs may isolate certain portions of the specification that use "subject" in the context of human clinical trials, the specifications also differentiate between "human subjects" and "non-human mammals." (*Id.* at 28-29.)

I construe "subject" to match Defendants' construction: "Mammal to whom the carbohydrate complex is administered." As a preliminary matter, while Plaintiffs have advised that the Court need not construe the "subject" term in connection with the '252 patent, the Court may nonetheless reference that term's use in the '252 patent to the extent it assists construction of the Helenek Family Patents. That said, the Court also acknowledges Plaintiffs' concern regarding this term; that is the Geisser Family Patents and the Helenek Family Patents are two separate patent families, with different inventors, different priority dates, and different POSAs.

Here, the intrinsic evidence cited by Defendants, including the claim language and the specification language, reveals that the term "subject" should not be limited to only humans. In that regard, the Court is not persuaded by Plaintiffs' argument that the term "subject" must be construed to mean "human" simply because the patents, specifically the Helenek Family Patents, are clinical patents. As explained by Defendants, the term "subject" is common to both the Helenek Family's '612 and '702 patents and the Geisser Family's '252 patent. With respect to the '252 patent, dependent Claim 18 is directed to "[a] method for treating an iron deficiency condition comprising the step of <u>administering to a subject</u> in need thereof a pharmaceutically effective amount of the medicament of [a prior claim]." Although "subject" does not appear in the specification of the '252 patent, the specification does unambiguously state that the "medicaments" containing the disclosed carbohydrate complexes "can be used in human and <u>veterinary medicine</u>."

Because claim interpretations that are contrary to the usage in the specification are erroneous, *Wi-Fi One, LLC v. Broadcom Corp.*, 887 F.3d 1329, 1346 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 826 (2019), I find that the "medicament" of Claim 18 must be construed consistent with Defendants' position—as one that can be used in human or veterinary medicine. As such, Plaintiffs' attempt to limit the term "subject" to only humans is not supported by the intrinsic evidence.

Similarly, as it pertains to the Helenek Family Patents, Claim 1 of the '612 and '702 patents states:

> A method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism resulting in reduced bioavailability of dietary iron, comprising administering to a subject in need thereof an iron carbohydrate complex . . . .

The Court agrees with Defendants that this claim language may be directly attributed to the following passage of the specification:

> methods of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism through the administration of at least 0.6 grams of elemental iron via a single unit dosage of an iron carbohydrate complex to a subject that is in need of such therapy.

(*See* '702 patent, 2:32-37; '612 patent, 2:37-43.) That same specification goes on to state that the invention applies to the treatment of a "state, disease, disorder, or condition" by preventing or delaying the appearance of clinical symptoms "in a mammal[.]" Accordingly, like the '612 and '702 patents, I find that a POSA would understand the term "subject" to mean something broader than just humans, *i.e.*, "mammals."

In addition, recent prosecution activity in related patent applications supports Defendants' construction. *Actelion Pharm., Ltd. v. Sun Pharm. Indus.*, No. 17-5015, 2019 WL 653149, at *6 (D.N.J. Feb. 15, 2019) ("[S]tatements made by the inventor during continued prosecution of a

related patent application can, in some circumstances, be relevant to claim construction."). For example, the recently filed patent application in U.S. Patent Application No. 16/825,337, which is related to the '612 patent, includes the phrase "adult human subject." Clearly, the decision to incorporate "human" in the application signals the potential for non-human subjects. As Defendants correctly articulate, if "subject" was limited to mean "human," as Plaintiffs claim here, Plaintiffs would have stated "adult subject" instead of "adult human subject" in the later applications. (Def. Opening Br. at 29.) Thus, adopting Plaintiffs' proposed construction would make the use of "human" in the phrase "adult human subject" redundant—*i.e.*, "adult human human." *See Pfizer Inc. v. Teva Pharm. USA, Inc.*, 855 F. Supp. 2d 286, 298 (D.N.J. 2012) (rejecting proposed construction because it "would thus render portions of the patents superfluous").

Because the construction is sufficiently clear based on the intrinsic evidence, I need not consider extrinsic evidence. *See Vitronics*, 90 F.3d at 1584. Accordingly, I construe the term "subject" to mean "mammal to whom the carbohydrate complex is administered."

IV. CONCLUSION

In light of the foregoing reasons, the Court construes the disputed claim terms as represented in the chart below:

Disputed Term	Construction
"maltodextrin"	"a mixture of saccharides of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds"
"one maltodextrin" / "each individual maltodextrin"	one/each "maltodextrin," as that term is defined by this Opinion, *i.e.*, one mixture of saccharides of variable length composed of chains of D-glucose units connected primarily by α-(1→4) glycosidic bonds
"the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component"	"a carbohydrate component resulting in a low risk of anaphylactoid/ hypersensitivity reactions, wherein a low risk is an incidence of adverse events lower than dextran"
"the iron carbohydrate complex has […] substantially no cross reactivity with antidextran antibodies"	"the iron carbohydrate complex … does not exhibit a substantial antibody/antigen immune response with antidextran antibodies"
"subject"	"Mammal to whom the carbohydrate complex is administered"

Dated: June 28, 2021

/s/ Freda L. Wolfson
Freda L. Wolfson
U.S. Chief District Judge